albahealth™

K020592

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

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Date Prepared: February 15, 2002

APR 0 3 2002

The following is a summary of safety and effectiveness for:

Proprietary Name: albahealth C.A.L.M. Sleeve

Common/Usual name: Gradient Compression Arm Sleeve

Classification Name: Stocking, Medical Support (per 880.5780)

The C.A.L.M. Sleeve is of circular knit construction, and is constructed from Nylon and Spandex yarns. The sleeve is intended to be worn on the arm, and covers the arm from wrist to 2" below the pivot point of the shoulder. The C.A.L.M. Sleeve is non-sterile, and is not intended to be sterilized in use.

The knit of the sleeve is graduated. The length of yarn knit in gradually increases from the wrist to the upper portion of the sleeve. This results in a sleeve with compression that decreases from the wrist to the upper arm portion of the sleeve.

The C.A.L.M. Sleeve yields 20 to 30 mmHg (millimeters Mercury) compression to the wrist area, with gradually decreasing compression through the upper arm. This is the same level of compression claimed for the Jobst Ready-to-Wear Arm Sleeve (510(k) #K991570) and the Juzo Expert Line Compression Arm Sleeve (510(k) # unknown). This gradient compression helps keep fluid from accumulating in the arm in cases of edema and lymphedema of the arm, and assists in maintenance of the size of the limb in patients undergoing treatment for these conditions.

Search of FDA's MAUDE database did not reveal any adverse events associated with compression arm sleeves. Search of the database under product code DWL identified 10 events associated with graduated compression products (such as anti-embolism and support stockings) designed for use on the leg. Summaries of these 10 adverse events are attached.

Also attached are articles documenting the benefits and effectiveness of compression garments in the treatment of edema and lymphedema.

HEALTH PRODUCTS DIVISION
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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. David Bowman
Technical Director
Alba-Waldensian, Incorporated
Healthcare Products Division
425 North Gateway Avenue
Rockwood, Tennessee 37854

APR 0 3 2002

Re: K020592
Trade/Device Name: Albahealth C.A.L.M. Sleeve, Model 59001
Regulation Number: 880.5780
Regulation Name: Gradient Compression Arm Sleeve
Regulatory Class: II
Product Code: DWL
Dated: February 15, 2002
Received: February 22, 2002

Dear Mr. Bowman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements

of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K020592

Statement of Indications for Use

Albahealth C.A.L.M. Sleeve – Catalog #59001
Gradient Compression Arm Sleeve

Indications:

To assist in limb size maintenance of patients with mild to moderate edema or lymphedema of the arm.

Patricia Cucenta

(Division Sign-Off)
Division of Dental, Infection Control,
General Hospital Devices
Number K020592